PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN FOR ONGENTYS/ONTILYV (OPICAPONE)

This is a summary of the risk management plan (RMP) for Ongentys / Ontilyv. The RMP details important risks of Ongentys / Ontilyv, how these risks can be minimised, and how more information will be obtained about Ongentys' / Ontilyv's risks and uncertainties (missing information).

Ongentys' / Ontilyv's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Ongentys / Ontilyv should be used.

This summary of the RMP for Ongentys / Ontilyv should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Ongentys' / Ontilyv's RMP.

I. The medicine and what it is used for

Ongentys / Ontilyv is authorised as adjunctive therapy to preparations of levodopa/ DOPA decarboxylase inhibitors (DDCI) in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations (see SmPC for the full indication). It contains opicapone as the active substance and it is given as oral hard capsule.

Further information about the evaluation of Ongentys' / Ontilyv's benefits can be found in Ongentys' / Ontilyv's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage:
https://www.ema.europa.eu/en/medicines/human/EPAR/ontilyv

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Ongentys / Ontilyv, together with measures to minimise such risks and the proposed studies for learning more about Ongentys' / Ontilyv's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;

- Important advice on the medicine's packaging;

- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;

- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including periodic safety update report (PSUR) assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of Ongentys / Ontilyv are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Ongentys / Ontilyv. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

List of important risks and missing information	
Important identified risks	• None
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

Not applicable.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

Not applicable.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Ongentys / Ontilyv.